Tetrahydrocannabinol compositions and methods . . ., Page 20 of 24

CLAIMS

20

We claim:

- 1. An injectable pharmaceutical composition comprising tetrahydrocannabinol, ethanol, water, and a
- 5 pharmaceutically acceptable amphiphilic excipient.
 - 2. A composition according to claim 1 further comprising a pharmaceutically acceptable excipient salt.
 - 3. A composition according to claim 1 further comprising a pharmaceutically acceptable excipient oil.
- 10 4. A composition according to claim 1 further comprising a pharmaceutically acceptable excipient antioxidant.
 - 5. A composition according to claim 1, wherein the concentration of tetrahydrocannabinol is, by mass, not greater than about 0.35%.
- 15 6. A composition according to claim 1, wherein the concentration of ethanol is, by mass, not greater than about 15%.
 - 7. A composition according to claim 1, wherein the concentration of water is, by mass, not greater than about 90%.
 - 8. A composition according to claim 1, wherein the amphiphilic excipient comprises at least one member of the group consisting of: Cremophor EL, Polysorbate 80,

Tetrahydrocannabinol compositions and methods . . ., Page 21 of 24

Poloxamer 407, Poloxamer 237, PEG 400, Pharmasolve, propylene glycol, and hydroxypropyl beta-cyclodextrin.

- 9. A composition according to claim 2, wherein the salt comprises sodium chloride or sodium hydroxide.
- 5 10. A composition according to claim 3, wherein the oil comprises corn oil.
 - 11. A composition according to claim 4, wherein the antioxidant comprises sodium metabisulfite or ascorbyl palmitate.
- 10 12. A composition according to claim 8, wherein the concentration of Cremophor EL is, by mass, not greater than about 20%.
 - 13. A composition according to claim 8, wherein the concentration of Polysorbate 80 is, by mass, not greater

than about 15%.

15

- 14. A composition according to claim 8, wherein the concentration of Poloxamer 407 is, by mass, not greater than about 2.5%.
- 15. A composition according to claim 8, wherein the
 20 concentration of Poloxamer 237 is, by mass, not greater
 than about 5%.
 - 16. A composition according to claim 8, wherein the concentration of PEG 400 is, by mass, not greater than about 20%.

- 17. A composition according to claim 8, wherein the concentration of Pharmasolve is, by volume, not greater than about 10%.
- 18. A composition according to claim 8, wherein the
 5 concentration of propylene glycol is, by mass, not greater than about 60%.
 - 19. A composition according to claim 8, wherein the concentration of hyroxypropyl beta-cyclodextrin is, by mass, not greater than about 30%.
- 10 20. A composition according to claim 9, wherein the concentration of the salt renders the composition essentially isotonic.
 - 21. A composition according to claim 9, wherein the concentration of sodium chloride is, by mass, about 0.9%.
- 15 22. A composition according to claim 10, wherein the concentration of corn oil is, by mass, not greater than about 10%.
 - 23. A method for manufacture of an injectable pharmaceutical composition comprising tetrahydrocannabinol,
- ethanol, water, and a pharmaceutically acceptable
 amphiphilic excipient, said method comprising the steps of:
 admixing tetrahydrocannabinol with ethanol to form a first
 mixture; admixing water with a pharmaceutically acceptable
 amphiphilic excipient to form a second mixture; and

admixing the first mixture with the second mixture to form a third mixture, wherein said third mixture comprises an intermediate or a finished product in the manufacture of the injectable pharmaceutical composition.

Tetrahydrocannabinol compositions and methods . . ., Page 23 of 24

5 24. A method of treating, lessening, or ameliorating emesis, anorexia, or chronic or AIDS-related wasting syndrome in a subject in which it is desired to treat, to lessen, or to ameliorate emesis, anorexia, or chronic or AIDS-related wasting syndrome, said method comprising administering to the subject a therapeutically effective amount of a composition according to claim 1.